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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.              |
|--|-------------|----------------------|---------------------|-------------------------------|
| 10/786,881   | 02/24/2004  | Mark L. Nelson       | PAZ-222CN           | 1902                          |
| 959  | 7590        | 12/05/2006           |                     | EXAMINER<br>QAZI, SABIHA NAIM |
| LAHIVE & COCKFIELD, LLP<br>ONE POST OFFICE SQUARE<br>BOSTON, MA 02109-2127 |             |                      | ART UNIT<br>1616    | PAPER NUMBER                  |

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|------------------------------|------------------------|---------------------|
|                              | 10/786,881             | NELSON              |
| Examiner                     | Sabiha Qazi            | Art Unit<br>1616    |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 10 November 2006.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-26 and 38-46 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-26 and 38-48 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_ .  
5)  Notice of Informal Patent Application  
6)  Other: \_\_\_\_\_

**Non-Final Office Action**

Claims 1-26 and 38-48 are pending. No claim is allowed at this time. Applicant's election of group III, claim 1-26 and a species without traverse is acknowledged. Restriction is now made Final. Amendments are entered.

**Summary of this Office Action dated Sunday, November 25, 2006**

1. Response to Remarks
2. Information Disclosure Statement
3. Copending Applications
4. Specification
5. 35 USC § 102(b) Rejection
6. 35 USC § 112 --- Written Description and New Matter Rejection
7. Double Patenting Rejection
8. Communication

**Response to Remarks**

- Applicant's election of group III and election of species is hereby acknowledged.
- In order to advance the prosecution method of use claims are rejoined and examined with the compounds.

**Information Disclosure Statement**

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

**Copending Applications**

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See *Dayco Products Inc. v. Total Containment Inc.*, 66 USPQ2d 1801 (CA FC 2003).

Applicant is kindly requested to show the relevancy of the claimed invention from the long list of copending applications and other references cited in the IDS submitted to the office.

### Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

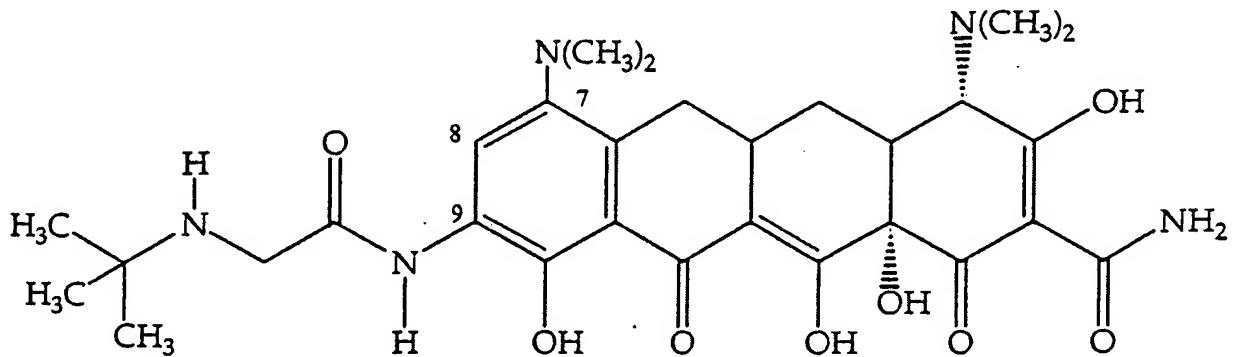
### 35 USC § 102(b) Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

*A person shall be entitled to a patent unless –*

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

Claims 1-7, 9, 10, 13-17 and 38-48 are rejected under 35 U.S.C. 102(b) as being anticipated by PETTERSEN et al. (Antimicrobial Agents and Chemotherapy, 1999, p-738-744 (IDS reference). See the Figure 1 on page 739. The compound in figure 1 has the following structure, which is the elected species.



1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 38, 45, 46 and 47 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. Claim 38 is drawn to a method for treating a tetracycline responsive state in a mammal, comprising administering to said subject a compound of claim 1, such that said subject is treated. Claims 46 and 47 are dependent on claim 38.

4. The tetracycline responsive state may include many known unknown diseases. At the time when the invention was made Applicants had no possession of such a treatment. One skilled in the art would have to go through undue experimentation to make and use the invention.

5. Claim 45 is drawn to the method of treating bacterial infection is resistant to other tetracycline antibiotics has no description. One skilled in the art would have to go through undue experimentation to make and use the invention. Applicant is kindly requested to tell the office about possession and description at the time of filing this application.

***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-26 and 38-48 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25, 36 and 37 of copending Application No. 11/069,197. Although the conflicting claims are not identical, they are not patentably distinct from each other because subject matter of the present claims has been claimed. Tetracycline compounds of the present invention overlaps with the claimed invention of the copending application. In claims of the present invention R9 is amino alkyl wherein copending application R9 can be various substituents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claimed subject matter

Claims are drawn to 9-aminoalkyl substituted tetracyclines and their method of use.

### **Communication**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D  
PRIMARY EXAMINER